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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/671,436	Applicant(s) BUCK ET AL.
	Examiner ALEX NOGUEROLA	Art Unit 1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 9/25/2003.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-59 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 25 September 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/14/2004.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3-5, 41-44, 46-48, 50-52, 54-56, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. (US 5,958,791).

Addresing claim 1, Roberts discloses a method for measuring the concentration of an analyte in a liquid sample, the method comprising contacting a volume of the liquid sample with

1) predetermined amount of a first redox reversible species, the species comprising a liquid sample diffusible conjugate of a liquid analog of an analyte in the liquid sample and a redox reversible label, the conjugate capable of competitive binding with a specific binding partner for the analyte (col. 11:50-62; col. 22:38-45 and col. 30:65 – col. 31:6. Note that the liposomes contain a redox reversible species, such as ferrocyanide (col. 21:36-44 and col. 31:7-8)), and

2) a predetermined amount of a specific binding partner for the analyte to be measured (col. 22:38-42, especially lines 41-42); and electrochemically determining the concentration of the diffusible redox-reversible species in the liquid sample by

contacting the sample with an electrode structure including a reference electrode and at least first and second working electrodes dimensioned to allow diffusional recycling of the diffusible redox species in the sample when a predetermined redox-reversible-species-dependent cathodic potential is applied to one working electrode and a predetermined redox-reversible-species-dependent anodic potential is applied to a second working electrode, the diffusional recycling of the species being sufficient to sustain a measurable current through the sample (col. 26:30-40; col. 7:66 – col. 8:37; Figure 3; and col. 30:50 – col. 31:55),

applying a first-cathodic potential to the first working electrode and a first anodic potential to the second working electrode, the first cathodic and anodic potentials corresponding to those respective potentials necessary to establish current flow through the sample due to diffusional recycling of the first redox reversible species (implied by col. 31:16-55, which discloses redox recycling of the first redox reversible species and measuring current), and

correlating the measured current flow to that for known concentration of the diffusible redox reversible species (col. 31:53-55).

Roberts does not describe in detail the example embodiment in which a second redox reversible species is also contacted with the sample and subjected to redox-recycling by the working electrodes with the resulting current flow measured and correlated to that for known concentrations of the second diffusible reversible species; however, it would have been obvious to one with ordinary skill in the art at the time of the invention to also include a second redox reversible species as this embodiment suggests because Roberts discloses a variety of redox reversible labels (col. 21:35-43) and does teach, "With the test devices and methods of the invention, one may also assay a test sample for *a plurality of analytes* such as toxic chemicals, or screen for one *or more of a plurality of analytes* ... In another embodiment, a single set of electrodes, preferably in a three-electrode configuration as shown and described above with reference to Fig. 3, can be used. The potential is varied, for example by scanning linearly with time, *to produce currents proportional to the different ion concentrations at unique potentials*"[emphasis added] (col. 25:15-28). So, with a second redox reversible

species another analyte in the sample can measured nearly simultaneously as the first analyte is measured.

As for each redox reversible species having a redox potential differing from the other by at least 50 milivolts, it would have been obvious to one with ordinary skill in the art at the time of the invention to select the redox species whose redox potentials differ as stated because this will avoid measurement inaccuracies due to accidental oxidation/reduction of the second redox-reversible species when only the first redox-reversible species should be oxidized or reduced, or vice-versa.

Addressing claims 3, 4, 50, and 51 for the additional limitations of this claim see col. 21:36-44. Redox reversible labels that meet claims 3 and 4 are disclosed by Roberts. As noted by the Roberts, "Suitable markers are those which are electrochemically active but will not degrade or otherwise leachout of the liposomes."

Addressing claims 5 and 52, as noted in the rejection of claim 1 Roberts discloses a variety of redox labels. Besides haying the reodx labels be compatible with the liposomes (Roberts col. 21:35-40), it would have been obvious to one with ordinary skill in the art at the time of the invention to have the respective redox potentials of the first and second redox-reversible species differ by at least 100 millivolts because this will avoid measurement inaccuracies due to accidental oxidation/reduction of the

second redox-reversible species when only the first redox-reversible species should be oxidized or reduced, or vice-versa.

Addressing claim 41, Roberts discloses a kit for measuring the concentration of one or more analytes in a liquid sample, the kit comprising

a redox reversible species for contact with the liquid sample, capable of diffusion in the liquid sample at least in the presence of a predetermined analyte, comprising a conjugate of a ligand analog of an analyte and a redox reversible label (col. 11:50-62; col. 22:38-45 and col. 30:65 – col. 31:6. Note that the liposomes contain a redox reversible species, such as ferrocyanide (col. 21:36-44 and col. 31:7-8)),

a specific binding partner for the analyte (col. 22:38-42, especially lines 41-42);

an electrode structure for contact with the liquid sample, the electrodes structure including a reference electrode and working electrodes dimensioned to allow diffusional recycling of diffusible redox reversible species in the sample when a predetermined redox-reversible-species-dependent-cathodic potential is applied to one working electrode and a predetermined redox-reversible-species-dependent-anodic potential is applied to the second working electrode, the diffusional recycling of the species means sufficient to sustain a measurable current through the sample; and conductors communicating with respective electrodes for applying the anodic potential and the

cathodic potential do for carrying current conducted by the electrodes (col. 26:30-40; col. 7:66 – col. 8:37; Figure 3; and col. 30:50 – col. 31:55).

Roberts does not describe in detail the example embodiment in which a second redox reversible species is also contacted with the sample and subjected to redox-recycling by the working electrodes with the resulting current flow measured and correlated to that for known concentrations of the second diffusible reversible species; however, it would have been obvious to one with ordinary skill in the art at the time of the invention to also include a second redox reversible species as this embodiment suggests because Roberts discloses a variety of redox reversible labels (col. 21:35-43) and does teach, "With the test devices and methods of the invention, one may also assay a test sample for *a plurality of analytes* such as toxic chemicals, or screen for one *or more of a plurality of analytes* ... In another embodiment, a single set of electrodes, preferably in a three-electrode configuration as shown and described above with reference to Fig. 3, can be used. The potential is varied, for example by scanning linearly with time, *to produce currents proportional to the different ion concentrations at unique potentials*"[emphasis added] (col. 25:15-28). So, with a second redox reversible species another analyte in the sample can measured nearly simultaneously as the first analyte is measured.

As for each redox reversible species having a redox potential differing from the other by at least 50 milivolts, it would have been obvious to one with ordinary skill in the art at the time of the invention to select the redox species whose redox potentials differ as stated because this will avoid measurement inaccuracies due to accidental

oxidation/reduction of the second redox-reversible species when only the first redox-reversible species should be oxidized or reduced, or vice-versa.

Addressing claims 42 and 43, for the additional limitations of these claims see Figures 1 and 2a and col. 23:27 – col. 24:15.

Addressing claim 44, for the additional limitations of this claim see col. 30:65 – col. 31:2 and col. 31:9-16, which discloses that the redox reversible species, which are in lipososmes, are mixed with the sample solution.

Addressing claims 46 and 47, as noted in the rejection of claim 41 Roberts discloses a variety of redox labels. Besides haying the redox labels be compatible with the liposomes (Roberts col. 21:35-40), it would have been obvious to one with ordinary skill in the art at the time of the invention to have the respective redox potentials of the first and second redox-reversible species differ by at least 100 millivolts or 200 millivolts because this will avoid measurement inaccuracies due to accidental oxidation/reduction of the second redox-reversible species when only the first redox-reversible species should be oxidized or reduced, or vice-versa.

Addressing claim 48, Roberts discloses a method for measuring the concentration of a first redox reversible species, the method comprising

electrochemically determining the concentration of the redox-reversible species in the liquid sample by

contacting the sample with an electrode structure including a reference electrode and at least first and second working electrodes dimensioned to allow diffusional recycling of the redox reversible species in the sample when a predetermined redox-reversible-species-dependent cathodic potential is applied to one working electrode and a predetermined redox-reversible-species-dependent anodic potential is applied to a second working electrode, the diffusional recycling of the species being sufficient to sustain a measurable current through the sample (see col. 26:30-40; col. 7:66 – col. 8:37; Figure 3; and col. 30:50 – col. 31:55. Note that col. 31:16-55, discloses redox recycling of the first redox reversible species and measuring current.),

measuring current flow at the first anodic and cathodic potentials (note that col. 31:16-55, discloses redox recycling of the first redox reversible species and measuring current), and

correlating the respective measured current flows to that for known concentrations of the respective diffusible redox reversible species (implied since the concentration of analyte in the sample is determined from the measurement signal due to current from redox recycling of the diffusible redox reversible species – col. 31:38-55).

Roberts does not describe in detail the example embodiment in which a second redox reversible species is also contacted with the sample and subjected to redox-recycling by the working electrodes with the resulting current flow measured and correlated to that for known concentrations of the second diffusible reversible species; however, it would have been obvious to one with ordinary skill in the art at the time of the invention to also include a second redox reversible species as this embodiment suggests because Roberts discloses a variety of redox reversible labels (col. 21:35-43) and does teach, "With the test devices and methods of the invention, one may also assay a test sample for *a plurality of analytes* such as toxic chemicals, or screen for one *or more of a plurality of analytes* ... In another embodiment, a single set of electrodes, preferably in a three-electrode configuration as shown and described above with reference to Fig. 3, can be used. The potential is varied, for example by scanning linearly with time, *to produce currents proportional to the different ion concentrations at unique potentials*"[emphasis added] (col. 25:15-28). So, with a second redox reversible species another analyte in the sample can measured nearly simultaneously as the first analyte is measured.

As for each redox reversible species having a redox potential differing from the other by at least 50 milivolts, it would have been obvious to one with ordinary skill in the art at the time of the invention to select the redox species whose redox potentials differ as stated because this will avoid measurement inaccuracies due to accidental oxidation/reduction of the second redox-reversible species when only the first redox-reversible species should be oxidized or reduced, or vice-versa.

Addressing claim 54, Roberts discloses a method of determining the amount or concentration of a redox-reversible species in solution, comprising

providing an electrochemical measurement cell comprising at least two working electrodes and a reference electrode, the working electrodes so configured and arranged that redox recycling of diffusible redox-reversible species takes place between the working electrodes when appropriate potentials are applied (col. 26:30-40; col. 7:66 – col. 8:37; Figure 3; and col. 30:50 – col. 31:55),

contact the solution with the electrodes in the measurement cell (Figures 1 and 3 and col. 31:17-55), and

applying potential to the working electrodes such that a current through the cell is generated as a result of redox recycling of at least one diffusible redox-reversible species (col. 31:17-55).

Roberts does not describe in detail the example embodiment in which a second redox reversible species is also contacted with the sample and subjected to redox-recycling by the working electrodes with the resulting current flow measured and correlated to that for known concentrations of the second diffusible reversible species; however, it would have been obvious to one with ordinary skill in the art at the time of the invention to also include a second redox reversible species as this embodiment suggests because Roberts discloses a variety of redox reversible labels (col. 21:35-43) and does teach, "With the test devices and methods of the invention, one may also assay a test sample for *a plurality of analytes* such as toxic chemicals, or screen for one *or more of a plurality of analytes* ... In another embodiment, a single set of electrodes,

preferably in a three-electrode configuration as shown and described above with reference to Fig. 3, can be used. The potential is varied, for example by scanning linearly with time, *to produce currents proportional to the different ion concentrations at unique potentials'*[emphasis added] (col. 25:15-28). So, with a second redox reversible species another analyte in the sample can measured nearly simultaneously as the first analyte is measured.

As for each redox reversible species having a redox potential differing from the other by at least 50 milivolts, it would have been obvious to one with ordinary skill in the art at the time of the invention to select the redox species whose redox potentials differ as stated because this will avoid measurement inaccuracies due to accidental oxidation/reduction of the second redox-reversible species when only the first redox-reversible species should be oxidized or reduced, or vice-versa.

Addressing claim 55, that the respective measured current flows correlate to the concentrations of the respective diffusible redox reversible species is implied since the concentration of analyte in the sample is determined from the measurement signal due to current from redox recycling of the diffusible redox reversible species – col. 31:38-55.

Addressing claim 56, for the additional limitation of this claim see col. 31:53-55 and col. 25:26-28.

Addressing claim 59, Roberts discloses a method for measuring the concentration of an analyte in a liquid sample, the method comprising

reacting a compound with the analyte to generate a first redox reversible species in the liquid (col. 31:32-36 and col. 22:38-67 – analyte-tagged liposomes are lysed in the lysis zone to release a redox reversible species) electrochemically determining the concentration of the redox-reversible species in the liquid sample by

contacting the sample with an electrode structure including a reference electrode and at least first and second working electrodes dimensioned to allow diffusional recycling of the redox reversible species in the sample when a predetermined redox-reversible-species-dependent cathodic potential is applied to one working electrode and a predetermined redox-reversible-species-dependent anodic potential is applied to a second working electrode, the diffusional recycling of the species being sufficient to sustain a measurable current through the sample (see col. 26:30-40; col. 7:66 – col. 8:37; Figure 3; and col. 30:50 – col. 31:55. Note that col. 31:16-55, discloses redox recycling of the first redox reversible species and measuring current.),

measuring current flow at the first anodic and cathodic potentials (note that col. 31:16-55, discloses redox recycling of the first redox reversible species and measuring current), and

correlating the respective measured current flows to that for known concentrations of the respective diffusible redox reversible species (implied since the concentration of analyte in the sample is determined from the measurement signal due to current from redox recycling of the diffusible redox reversible species –

col. 31:38-55).

Roberts does not describe in detail the example embodiment in which a second redox reversible species is also contacted with the sample and subjected to redox-recycling by the working electrodes with the resulting current flow measured and correlated to that for known concentrations of the second diffusible reversible species; however, it would have been obvious to one with ordinary skill in the art at the time of the invention to also include a second redox reversible species as this embodiment suggests because Roberts discloses a variety of redox reversible labels (col. 21:35-43) and does teach, "With the test devices and methods of the invention, one may also assay a test sample for *a plurality of analytes* such as toxic chemicals, or screen for one *or more of a plurality of analytes* ... In another embodiment, a single set of electrodes, preferably in a three-electrode configuration as shown and described above with reference to Fig. 3, can be used. The potential is varied, for example by scanning linearly with time, *to produce currents proportional to the different ion concentrations at unique potentials*"[emphasis added] (col. 25:15-28). So, with a second redox reversible species another analyte in the sample can measured nearly simultaneously as the first analyte is measured.

As for each redox reversible species having a redox potential differing from the other by at least 50 milivolts, it would have been obvious to one with ordinary skill in the art at the time of the invention to select the redox species whose redox potentials differ as stated because this will avoid measurement inaccuracies due to accidental

oxidation/reduction of the second redox-reversible species when only the first redox-reversible species should be oxidized or reduced, or vice-versa.

5. Claims 2, 6, 49, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. (US 5,958,791) as applied to claims 1, 3-5, 41-44, 46-48, 50-52, 54-56, and 59 above, and further in view of Niwa et al. ("Voltammetric Measurements of Reversible and Quasi-Reversible Redox Species Using Carbon Film Based Interdigitated Array Microelectrodes," Anal. Chem. 1994, 66, 285-289) ("Niwa").

Addressing claims 2 and 49, Roberts does not mention using a bipotentiostat; however, Niwa, which Roberts Incorporates by reference in regard to redox recycling (col. 8:19-24) does (Experimental Section – Apparatus on page 286). It would have been obvious to one with ordinary skill in the art at the time of the invention to use a bipotentiostat as taught by Niwa in the invention of Roberts because, besides being incorporated by reference by Roberts, it would allow independent control of the potentials at the working electrodes so that the redox recycling can be optimized.

Addressing claims 6 and 53, Roberts does not mention measuring the current flow as at least one of the anodic or cathodic potentials is held at the predetermined value and the potential of the other is swept through its predetermined value.

Niwa discloses a method for measuring reversible and quasi-reversible redox species using carbon film based interdigitated array microelectrodes. The method involves mention measuring the current flow as at least one of the anodic or cathodic potentials is held at the predetermined value and the potential of the other is swept through its predetermined value. See the title, abstract, and Experimental Section – Procedure (generation-collection voltammetry measurement) on page 286.

It would have been obvious to one with ordinary skill in the art at the time of the invention to measure the current flow as at least one of the anodic or cathodic potentials is held at the predetermined value and the potential of the other is swept through its predetermined value as taught by Niwa in the invention of Roberts because besides being incorporated by reference by Roberts (col. 8:19-24), an accurate measurement can be made on a small amount of redox species (abstract and second through fourth paragraph in the first column on page 288).

6. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. (US 5,958,791) as applied to claims 1, 3-5, 41-44, 46-48, 50-52, 54-56, and 59 above, and further in view of Spring et al. (US 5,643,721) ("Spring").

Roberts does not mention having the ligand analog component of the first redox-

reversible –species be a peptide comprising an epitope of a first analyte and the ligand analog component of a second redox-reversible-species be a peptide comprising the epitope of a second analyte.

Spring discloses a bioreagent immobilization medium for an electrochemical sensor that includes "a synthetic peptide sequence which duplicates at least one epitope of the whole molecule analyte so that the analyte –analog can bind to an analyte-specific binding member." See col. 6:21-36 and col.4:5-15.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use a ligand analog comprising an epitope of an analyte as taught by Spring in the invention of Roberts because this will increase the selectivity of the ligand analog for the analyte as an epitope is a specific region of an antigen that will combine with a specific antibody. Since there are two ligand analog components it would have been obvious to use two ligand analogs each comprising an epitope, a different ligand analyte as appropriate for each analyte.

7. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. (US 5,958,791) as applied to claims 1, 3-5, 41-44, 46-48, 54-56, and 59 above, and further in view of Deng et al. (US 5,589,326) ("Deng").

Although Roberts discloses a variety of redox reversible species Roberts does not mention one comprising an osmium complex.

Deng discloses osmium-containing redox mediators for uses in electrochemical biosensors. See the abstract.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an osmium-containing redox mediator as taught by Deng in the invention of Roberts because as taught by Deng "[t]hese compounds possess the following advantageous combination of characteristics: 1) a low oxidation potential, ..., 3)slow oxidation of osmium by oxygen, an d4) excellent solubility in aqueous medium." See col. 3:49-55.

Claim Rejections - 35 USC § 112

8. Claims 9, 10, and 41-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 9 - it is not clear that claim 1 actually requires first and second ligand analog components as claim 1 only states "at least one species comprising a liquid sample diffusible conjugate of a ligand analog of an analyte ..."

b) Claim 41 recites the limitation "said species means" in line 20. There is insufficient antecedent basis for this limitation in the claim.

9. Note that dependent claims will have the deficiencies of base and intervening claims.

Allowable Subject Matter

10. Claims 11-40 and 58 will be allowed when the Reissue formalities discussed in the subsequent section of this Office action have been met.

11. Claims 9 and 10 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims and if the Reissue formalities discussed in the subsequent section of this Office action have been met.

12. Claim 57 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and if the Reissue formalities discussed in the subsequent section of this Office action have been met.

13. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 9: the combination of limitations requires the respective ligand analog component of the first and second redox-reversible-species to be different ligand

analogs of a single analyte. This allows two independent measurements to be performed on a single analyte. See column 11, lines 1-4 in US 6,294,062 B1.

In Roberts the respective ligand analog component of the first and second redox-reversible-species would each be for a different analyte.

b) Claim 11: the combination of limitations requires the device to comprise "a sample chamber for holding the liquid sample." As disclosed by Applicants, "The electrode structure can be formed on an inner surface of a chamber for receiving the liquid sample, e.g., a cuvette, a capillary fill chamber, or other receiving vessel wherein the electrode structure can be contacted with the liquid sample." See column 8, lines 40-45.

In contrast, in Roberts the device for detecting or quantifying one or more analytes in a liquid sample does not have a sample chamber, it is separate from the device. The device of Roberts comprises a support (114) on which two absorbent strips (112) are placed in parallel. One end of the device is placed into a sample chamber of a tray (110) so that sample and redox reversible species, which are in lipososmes, are drawn by capillary action from the chamber into the absorbent strips and through two chemical treatment regions (104,106) in each strip until the electrode structure is reached and electrochemical measurement can be made. See Figure 1 and col. 14:65 – col.15:35 and col. 14:13-35.

c) Claims 12-40 depend directly or indirectly from allowable independent claim 11.

d) Claim 57: the combination of limitations requires the measured concentration of one species to be corrected by the repsonse of another species. In Roberts the response of each species is used to separately determine the concentration of a particular analyte. See col. 31:53-55 and col. 25:22-28.

e) Claim 58 is a method of determining the relative diffusion coefficients of a plurality of diffusible redox-reversible species in a solution. Roberts' method is for determining the concentration of analyte in a sample. The current produced by redox recycling of the redox-reversible species are correlated to the concentration of an analyte, such as pesticides, drugs, hormones, and antibodies. See the abstract; col. 25:46-62; col. 25:26-28; and col. 31:53-55.

f) US 5,589,326 A (Deng et al.) was cited as an "X" reference against claims 1-7 in the International Search Report for International Application No. PCT/US99/11855. Deng et al. discloses osmium compounds useful as redox mediators for electrochemical biosensors. Unlike claim 1, in Deng et al. is no teaching or suggestion of diffusional recycling of a diffusible redox-reversible-species, electrodes dimensioned to allow such recycling, and contacting the

liquid sample with predetermined amounts of a first and second redox reversible species.

Reissue Formalities

14. This application is objected to under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. The consent of the assignee must be in compliance with 37 CFR 1.172. See MPEP § 1410.01.

A proper assent of the assignee in compliance with 37 CFR 1.172 and 3.73 is required in reply to this Office action.

The consent of assignee submitted by applicants is not sufficient. Applicants use the language "hereby assents to the accompanying DECLARATION BY INVENTORS." MPEP 1410.01 gives an example of acceptable language:

The XYZ Corporation, assignee of U.S. Patent No. 9,999,999, consents to the filing of reissue application No. 09/999,999 (or the present application, if filed with the initial application papers) for the reissue of U.S. Patent No. 9,999,999.

15. The reissue oath/declaration filed with this application is defective because it fails to contain a statement that all errors which are being corrected in the reissue application up to the time of filing of the oath/declaration arose without any deceptive intention on the part of the applicant. See 37 CFR 1.175 and MPEP § 1414.

37 CFR 1.175(a)(2) states that all errors corrected in the reissue application up to the filing of the oath or declaration arose without deceptive intention on the part of the applicant. The instant declaration basically states that errors that render the instant patent inoperative arose without deceptive intent. This is not the same as "all errors corrected".

16. Claims 1-59 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defects in the declaration is set forth in the discussion above in this Office action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
June 13, 2006